REMARKS

This Response is in reply to the Final Office Action dated January 3, 2008 and is filed after the filing of a Notice of Appeal on June 2, 2008. Filed concurrently herewith is the Rule 1.132 Declaration of Dr. Klaus Henning (hereinafter, the "Henning Declaration"). Applicants believe that the Henning Declaration (1) overcomes all rejections under appeal, (2) is necessary to present the unexpectedly superior storage effects possessed by the claimed starch products, and (3) could not have been presented to the Examiner earlier, since Applicants required additional time for Dr. Henning to design and perform the toxicokinetic study described in his declaration, analyze the data generated by the study, and prepare his declaration. MPEP § 1206(II)

Entry of this Response and the Henning Declaration and reconsideration of the application in view of the same is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 5-8, 11, and 13 stand rejected as obvious over U.S. Patent No. 5,218,108 to Sommermeyer et al. (hereinafter "Sommermeyer II") in view of U.S. Patent Application Publication No. 2002/0065410 to Antrim (hereinafter "Antrim"). Claims 1, 2, 4, 6-8, 10, and 12 stand rejected as obvious over U.S. Patent No. 6,284,140 to Sommermeyer et al. (hereinafter "Sommermeyer III") in view of Antrim. Claim 9 stands rejected as obvious over either of Sommermeyer II or Sommermeyer III, both in view of Antrim and in further view of WO 00/33851 A1 to Naggi et al. (hereinafter "Naggi"). Applicants respectfully traverse.

Rejection of Claims 1, 2, 5-8, 11, and 13 Over Sommermeyer II in View of Antrim

The Examiner maintains this rejection on the grounds that (1) Sommermeyer II teaches a hydroxyethyl starch having all of the limitations of these claims except for the recited degree of branching in the range of from 8-20 mol %, (2) Antrim teaches this missing limitation, and (3) persons of ordinary skill in the art would have been motivated to combine the teachings of Sommermeyer II and Antrim in the manner proposed by the Examiner because "Antrim

discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications." *See* page 3, line 20 to page 5, line 3 of the January 3, 2008 Office Action. Applicants respectfully disagree.

Applicants maintain that claims 1, 2, 5-8, 11, and 13 are non-obvious and patentable over the combined teachings of Sommermeyer II and Antrim for the reasons presented in Applicants' November 13, 2007 Amendment and incorporate those remarks herein by reference in their entirety.

Furthermore, claims 1, 2, 5-8, 11, and 13 are non-obvious and patentable over the combined teachings of these references because the claimed starch products possess unexpectedly superior storage effects compared to starch products that possess conventional degrees of branching. A *prima facie* case of obviousness is rebuttable by evidence that the claimed invention possesses unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381 (CCPA 1963). As is clear from paragraphs 1-4 of the Henning Declaration, Dr. Henning is an expert in the field of carbohydrate chemistry, with particular expertise in starch products for use as volume expanders. A toxicokinetic study was performed at the direction of Dr. Henning, which compared the storage effects of three starch products having degrees of branching within the claimed range of 8 to 20 % to those of three starch products with conventional degrees of branching of approximately 5%. The data presented in the table in paragraph 7 of the Henning Declaration clearly demonstrates that starch products having degrees of branching within the claimed range possess unexpectedly superior storage effects, since, as explained in paragraph 8 of the Henning Declaration, persons of ordinary skill in the art would have expected an increased storage effect for the more highly branched starches IE 1 and IE 2 compared to CE 1. This unexpectedly superior storage effect is attributable to the higher than conventional degree of branching, since this effect is independent of degree of substitution, as explained in paragraph 9 of the Henning Declaration. In view of the data and analysis presented in the Henning Declaration, the starch products of the present claims clearly exhibit an unexpectedly and substantially smaller tissue storage effect after 8 hours compared to starch products with a conventional degree of branching. Persons of ordinary skill in the art would not

have expected the starch products disclosed in Sommermeyer II, which would possess a conventional degree of branching, to exhibit the same tissue storage effect. As such, since claims 1, 2, 5-8, 11, and 13 are non-obvious and patentable over the combined teachings of Sommermeyer II and Antrim, Applicants respectfully request withdrawal of this rejection.

Rejection of Claims 1, 2, 4, 6-8, 10, and 12 Over Sommermeyer III in View of Antrim

The Examiner maintains this rejection on the grounds that (1) Sommermeyer III teaches a hydroxyethyl starch having all of the limitations of these claims except for the recited degree of branching in the range of from 8-20 mol %, (2) Antrim teaches this missing limitation, and (3) that persons of ordinary skill in the art would have been motivated to combine the teachings of Sommermeyer III and Antrim in the manner proposed by the Examiner because "Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications." *See* page 6, line 1 to page 7, line 8 of the January 3, 2008 Office Action.

Applicants maintain that claims 1, 2, 4, 6-8, 10, and 12 are non-obvious and patentable over the combined teachings of Sommermeyer III and Antrim for the reasons presented in Applicants' November 13, 2007 Amendment and incorporate those remarks herein by reference in their entirety.

Furthermore, claims 1, 2, 4, 6-8, 10, and 12 are non-obvious and patentable over the combined teachings of these references because the claimed starch products possess unexpectedly superior storage effects compared to starch products that possess conventional degrees of branching. Applicants incorporate herein by reference the remarks *supra* regarding the Henning Declaration. In view of the data and analysis presented in the Henning Declaration, the starch products of the present claims clearly exhibit an unexpectedly and substantially smaller tissue storage effect after 8 hours compared to starch products with a conventional degree of branching. Persons of ordinary skill in the art would not have expected the starch products disclosed in Sommermeyer III, which would possess a conventional degree of branching, to exhibit the same tissue storage effect. As such, since claims 1, 2, 4, 6-8, 10, and 12

are non-obvious and patentable over the combined teachings of Sommermeyer III and Antrim, Applicants respectfully request withdrawal of this rejection.

Rejection of Claim 9

The Examiner maintains this rejection on grounds that (1) the combined teachings of either Sommermeyer II and Antrim or Sommermeyer III and Antrim disclose a hydroxyethyl starch having all of the limitations of claim 9 except for a starch in which the reducing end has been inactivated by oxidation or reduction; (2) Naggi teaches this missing limitation; and (3) that persons of ordinary skill in the art would have been motivated to combine the teachings of either Sommermeyer II and Antrim or Sommermeyer III and Antrim with Naggi in the manner proposed by the Examiner because Naggi discloses that inactivating the reducing end via oxidation or reduction "allows the starch to be autoclaved without forming toxic degradation products such as formaldehyde." *See* page 8, line 6 to page 9, line 7 of the January 3, 2008 Office Action.

Applicants maintain that claim 9 is non-obvious and patentable over the combined teachings of either Sommermeyer II, Antrim, and Naggi or Sommermeyer III, Antrim, and Naggi for the reasons presented in Applicants' November 13, 2007 Amendment and incorporate those remarks herein by reference in their entirety.

Furthermore, claim 9 is non-obvious and patentable over the combined teachings of these references because the claimed starch products possess unexpectedly superior storage effects compared to starch products that possess conventional degrees of branching. Applicants incorporate herein by reference the remarks *supra* regarding the Henning Declaration. In view of the data and analysis presented in the Henning Declaration, the starch products of the present claims clearly exhibit an unexpectedly and substantially smaller tissue storage effect after 8 hours compared to starch products with a conventional degree of branching. Persons of ordinary skill in the art would not have expected the starch products disclosed in Sommermeyer II or Sommermeyer III, which would possess a conventional degree of branching, to exhibit the same tissue storage effect. As such, since claim 9 is non-obvious and patentable over the combined

teachings of either Sommermeyer II, Antrim, and Naggi or Sommermeyer III, Antrim, and Naggi, Applicants respectfully request withdrawal of this rejection.

In view of the foregoing remarks, Applicants believe the pending application is in condition for allowance.

The Director is authorized to charge $460.00 to Deposit Account No. 03-2775, under Order No. 09600-00028-US, to cover the extension fee required by 37 C.F.R. § 1.17(a)(2). Should any other fees be required in connection with this response, the Director is hereby authorized to charge any fees due or outstanding, including any extension fees, or credit any overpayment, to Deposit Account No. 03-2775, under Order No. 09600-00028-US, from which the undersigned is authorized to draw.

Dated: October 2, 2008

Respectfully submitted,

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